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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ALEXANDER, LYLE	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
09/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,290	OPALSKY ET AL.	
	Examiner	Art Unit	
	Lyle A. Alexander	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *90-96,98-126,128-167,173 and 174* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *90-96, 98-126, 128-167 and 173-174* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 90-96, 98-126, 128-167 and 173-174 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The 5/22/08 amendments add the new claim language "disposed between a pump and the holding chamber" which does not appear to be supported by the original disclosure. The 5/22/08 remarks state the new claim language is supported by figures 2 and 5 as well as the associated text. The Office has considered figures 2 and 5 as well as pages 14-19 of the original specification that describe these figures. The Office did not find support for the claim language "disposed between a pump and the holding chamber."

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 90-96, 98-126 and 128-167 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 90 the language claim language "disposed between a pump and the holding chamber" has been added to the preamble but does not appear in the body of the claim. If the structural relationship between the overflow chamber, holding chamber and pump are not in the body of the claim, it is not clear how much weight to give these limitations. Furthermore, the body of the claim does not specify the flow of the sample from the pump, through the overflow chamber and ultimately in the holding chamber. For the purposes of examination, it will be assumed the sample flows from the pump to the over flow chamber and finally to the holding chamber.

Claim 108 does not appear to further limit the method of claim 90 because it is directed to the method of making the holding chamber and should be deleted. Clarification could be achieved by incorporating similar amendments that were made to claim 119.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 90-96, 98-126, 128-167 and 173-174 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-107 and claims 1-47 of U.S. Patent No. 6,750,053 and 6,438,498 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because are directed to placing the sample in a holding chamber, metering off the overflow from the holding chamber, metering the sample to an analysis location, mixing the sample with a reagent, etc. The 6,750,053 patent is related to the instant application as a continuation and not as a divisional which is why the patent is available for this double patenting rejection (e.g. there was no restriction requirement made in the patent).

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 173-174 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Handique et al. (USP 6,130,098).

Handique et al. (USP 6,130,098) teach a method of detecting a reaction product where a sample is introduced into a holding chamber, excess sample removed, and reagents added and mixed. The resultant reaction is detection and the analyte of interest is quantified. There is a stop junction to control the fluid flow and a hydrophobic region. Handique et al. (USP 6,130,098) additionally teaches in columns 17-18 lines

63-68 respectively silicon dioxide surface and in column 26 line 20 teach a digestion buffer. Furthermore, column 16 lines 40+ teaches fluid control with sealed valves that have been read on the claimed "sealing the holding chamber with a ... after step(a)". The Office maintains there will be air pressure created by the pump and has been properly read on the claimed "pumping air."

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Sakisako et al. teach an automatic titration method to control an etching liquid that comprises hydrogen peroxide and sulfuric acid. The sample is pumped by pump(1) to an overflow chamber(2) which is further connected to a sample container(3). This reference fails to teach or suggest the claimed method of detecting a product in a blood sample.

Negersmith teaches a liquid sample analyzer that adds a reagent to a blood sample and subsequent analysis. Negersmith fails to teach or suggest the claimed method where the overflow chamber is disposed between the pump and the holding chamber.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797